

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Kevin P. CONNORS et al.

Application No.: 10/789,139

Confirmation No.: 9270

Filed: February 27, 2004

Art Unit: 3769

For: SYSTEM AND METHOD FOR HEATING
SKIN USING LIGHT TO PROVIDE TISSUE
TREATMENT

Examiner: David M. Shay

DECLARATION OF MACRENE ALEXIADES-ARMENAKAS

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I, Macrene Alexiades-Armenakas, declare as follows:

1. I am an M.D., with a Ph.D. in genetics. I received my undergraduate degree and my Ph.D. from Harvard University and my M.D. from Harvard Medical School. I was a Fulbright Scholar with a research award year in Europe.

2. I was dermatology resident at New York University School of Medicine and served as Chief Resident. I am a Fellow of both the American Academy of Dermatology and the American Society for Laser Medicine and Surgery. I am Board Certified in Dermatology.

3. I am currently an attending physician at Lenox Hill Hospital, Yale New Haven and Yale West Haven VA Hospitals. I am an assistant Clinical Professor at Yale University School of Medicine. A copy of my curriculum vitae is attached as Exhibit A.

4. I founded and direct a dermatology, laser surgery and research center. At the research center, I have run studies associated with the FDA trials for virtually every

new commercial product developed over the last ten years for skin tightening. In particular, I have run studies on the Thermacool system from Thermage, the Polaris, Galaxy, and ST Refirme systems from Syneron, the Accent system from Alma Lasers, the 1310 nm laser system from Candela, and the Miratone system by Primaeva. I have also conducted a study on the Titan system from Cutera which I understand is the subject of this patent application. I developed the first classification and grading scale for skin laxity and rhytides that has been utilized by several laser companies for quantitative grading of skin tightening devices. In addition, I ran the first "Skin Tightening Technologies" course at the American Academy of Laser Medicine and Sciences annual meeting. I believe I am a person that is highly skilled in the art to which this patent application pertains.

5. I consider myself an independent researcher for a large number of dermatology system manufacturers. I am not a paid consultant for any one dermatology company. I am compensated for the studies I perform for the various companies. Over time, I have been asked to participate on the medical advisory boards of various companies. In the case of Cutera, I participated in an advisory capacity for a fractional resurfacing product. I will be paid by Cutera for the hours I spend reviewing the material related to this declaration. I own no stock in Cutera and I have no stake in the outcome of this proceeding. The views expressed in this declaration are based on my extensive training in dermatology, my research experience evaluating various dermatology treatment protocols and my particular expertise in evaluating dermatology systems used for skin tightening.

6. Prior to making this declaration, I reviewed the above identified patent application, the currently pending Office Action and the prior art referenced in that Office Action. As discussed below, in my opinion as one skilled in the art, the method as defined in the pending independent claim 15 is not obvious from any combination of the prior art cited by the Examiner in the pending Office action.

7. As I understand it, claim 15 describes a method of tightening the skin wherein broadband radiation having wavelengths principally between 1050nm and 1850nm is transmitted to the skin through a cooled transmissive window. The treatment time is between 1.2 and five seconds in order to heat a volume of the skin between a

depth between 1mm and 5mm to at least 50° C while maintaining the shallower regions of the dermis at a temperature below the treatment temperature.

8. It is my understanding that the Cutera Titan system generates broadband radiation having wavelengths principally between 1050nm and 1850 which is delivered to the skin through a cooled transmissive window. I investigated the operation of the Titan device operating with the parameters described in the method of claim 15 in order to tighten the skin. Based on my observations, it is my belief that the treatment parameters of the Titan device, particularly with respect to the wavelength range, are important for the ability of the product to tighten the skin. It is my belief that these treatment parameters which are set forth in the method of claim 15 are not obvious based on the teachings of the prior art.

9. In my studies, I have observed that the Titan device provides very consistent and very reproducible skin tightening effects. I am of the belief that a likely explanation for this performance is based on the selection of an optimal treatment wavelength range, which produces deeper heating and induces ne elastogenesis. At the time of my research with the Titan, I had not previously observed this consistent a skin tightening result with prior light based treatment systems, which I believe tended to deposit more energy in the upper regions of the skin and have only been shown to generate neocollagenesis.

10. It is my understanding that claim 15 has been rejected as being unpatentable over Anderson (U.S. 6,120,497), Altshuler (US 2004/0093042) and Altshuler (US 2002/10763780).

11. Anderson relates to a method of treating skin wrinkles. His primary teaching relates to treatment with a single wavelength generated by a laser system. He briefly mentions that the source could generate "incoherent radiation." When discussing treatment parameters, he suggests that the beam has a wavelength between 1.3 and 1.8 microns, which to my reading suggests a single wavelength within this range. Anderson then gives examples of various laser systems that can generate light that emits a wavelength in this range. Taken as a whole, this disclosure teaches the use of a single wavelength treatment and does not suggest a treatment method using broadband light. The mere reference in the specification that the light source used to generate the desired

wavelength could be an incoherent source is ambiguous since the output of an incoherent source can be filtered to generate narrowband light. I note that the concept of treatment with broadband of radiation does not appear in Anderson disclosure. In my view, Anderson fails to teach treating tissue with broadband radiation having a range of 1050 to 1850nm.

12. Altshuler '042 relates to treating tissue with optical radiation. Altshuler '042 discusses using a broad spectrum lamp for treatment. In paragraph [0093], Altshuler '042 discusses some preferred wavelength ranges, specifically, between 800 and 1800nm, between 900 and 1400nm and between 1100 and 1250nm. None of these ranges mentioned in Altshuler '042 corresponds to the range restricted to 1050 to 1850nm, recited in claim 15. The claimed restriction to a wavelength range of 1050 to 1850nm is important because if one utilized the wavelength ranges specified by Altshuler, the depth of penetration and skin tightening results observed with Titan would have been unlikely to be achieved. Wavelengths spanning 800-1000 nm result in much vascular and pigment absorption, limiting the fluence and number of passes one can safely administer, and thereby preventing adequate heat deposition into deeper dermis. The 900 to 1400 nm range would likely result in similar complications and side effects as aforementioned and allow only superficial dermal injury. Finally, the 1100-1250 nm range would also result in only superficial dermal thermal injury and possibly little skin tightening, if any. Thus, it is my belief that none of the three ranges specified by Altshuler '042 would work in a manner similar to the claimed 1050 to 1800nm range. In my opinion as one skilled in the art, I would not have been motivated to develop a skin tightening method that utilized broadband radiation having a range between 1050 to 1800nm range based on the teachings in Altshuler '042 either alone or in combination with the teachings in Anderson.

13. In the Office Action, the Examiner pointed out that Altshuler '042 discloses irradiation times from approximately 2 seconds to approximately 2 hours. The Examiner states that these treatment times overlap the claimed treatment times and "one skilled in the art would use a time appropriate to achieve the desired temperature based on the operating parameters of the radiation source." I disagree. Perhaps one of the least obvious aspects of the claimed method relates to the determination of the optimal

irradiation time. The claimed 1.2 to 5 second treatment time has done much to contribute to our knowledge in determining optimal time-at-temperature parameters that are necessary to induce neocollagenesis and neoclastogenesis. In my opinion, the claimed 1.2 to 5 second treatment time would not have been obvious in view of the long treatment time (2 second to 2 hours) suggested by Althshuler '042 nor would it have been generally obvious to one skilled in the art.

14. Althshuler '780 also relates to treating tissue with optical radiation. The bulk of the disclosure in Althshuler '780 is directed to hair removal. Althshuler '780 includes a few paragraphs (beginning at paragraph [0088]) which discuss skin rejuvenation. For skin rejuvenation, Althshuler suggests treatment with broadband light having the wavelength range illustrated in Figure 7c. The range of wavelengths shown in Figure 7c spans from just about 900nm to 2.5 microns. It is my opinion that a method for skin tightening which treated tissue with broadband light having a range of 1050 to 1800nm would not be obvious in view of the teachings of Althshuler '780 either alone or in combination with either Anderson or Althshuler '042. Skin tightening targets the deep levels of dermis. In my view, a range of wavelengths spanning 900 nm to 2.5 would be problematic both due to vascular and pigment absorption and on the other end of the spectrum, possible penetration to adipose tissue. Once again, the claimed restriction to 1050 to 1800 nm wavelength range has in retrospect been shown to be ideal in thermal injury restricted to dermis and extending into deep dermis, without the problems of epidermal, vascular or fatty injury.

15. It is my understanding that the Examiner cited two additional prior art references for their teachings of features in the claims other than claim 15. U.S. Patent 5,885,274 to Fullmer was cited for its disclosure of using a simmer voltage to maintain the temperature of the lamp filament. U.S. Patent Publication 2005/10107850 to Vaynberg was cited for its teaching of a light sensor for providing feedback to alter the pulse parameters. In my opinion, neither Fullmer nor Vaynberg overcome the deficiencies of the above discussed prior art documents with respect to the patentability of claim 15.

16. Fullmer relates a device wherein a filament lamp is proposed for dermatological treatments. At column 7, line 57, Fullmer suggests using light having a

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range of 850 to 1800nm in order to modify collagen. Once again, too much pigment absorption from wavelengths below 1050nm would greatly limit the power output and number of passes that could safely be employed, and resulting in little if any skin tightening.

17. Vaynberg relates to a device for treating tissue with a pulsed incoherent light source. In paragraph [0016], it is stated that the lamp can generate an output between 300 and 1100nm. Paragraph [0031] suggests using a treatment pulse having a wavelength range of 400 to 600nm. Paragraph [0035] discusses how the spectral output of the lamp can be varied by varying the current supplied to the lamp. Figure 4A, 4B and 4C illustrate different spectral distributions. All three output spectra have significant portions below 1050nm. As discussed above these wavelength ranges would not work well because of inadequate energy deposition into the target tissue, i.e. deep dermis necessary for skin tightening.

18. In summary, none of the prior art of record teaches the method of claim 15 wherein skin tightening is performed using a broadband spectrum of radiation having a wavelength range between 1050nm and 1850nm along with the other limitations of the claim. More importantly, as one skilled in the art, it is my opinion that all of the prior art, even if combined, would not render obvious the subject matter of claim 15.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: 2/10/10

Macrene Alexiades-Armenakas
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